PhUSE 2014

DH03 - SDTM in Business Intelligence

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Agenda

Data Warehouse Principles

Domains as Dimensions

Using SDTM Domains for Data Pooling

Birth of a Star Schema

Populating a Fact Table

Derived Variables and Analyses – Definers

Dashboards and Delivery – Consumers

Dashboards and Delivery – Reconciliation

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Background: Increasing Demands on Clinical Development

Growing
volumes
of data

More
global
in scale

Increasing
regulatory
scrutiny

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Data Warehouse Principles

Large scale, reporting focused applications:

High volumes of aggregated data from multiple upstream transactional systems

Simplified point in time reporting and historical audit capability

Instant analyses without programming

Integration of varied analysis tools

Dashboards of common reports

Self service reporting

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Domains as Dimensions

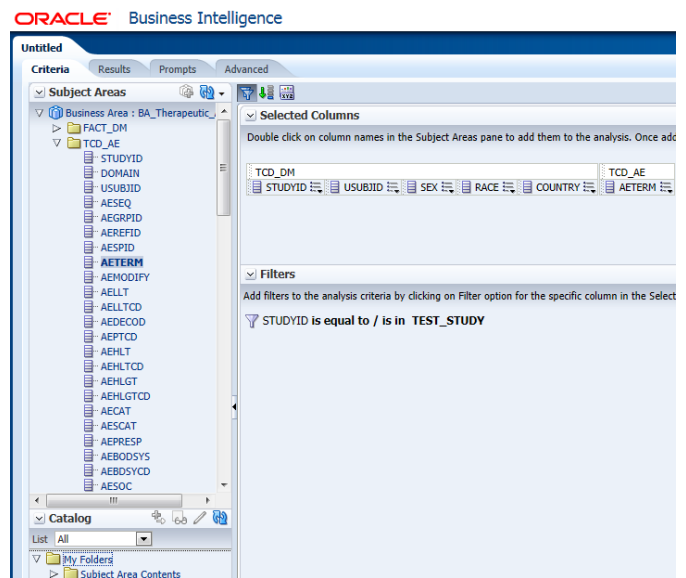SDTM as a presentation format is familiar, well understood:

Domains evolve, but are well defined and rarely updated

Domains are further extendable with SUPP Domains

Variables do not change

Consistent timing variables

Domains are key controlled

Using SDTM Domains for Data Pooling

SDTM keys allow the warehouse to:

1. Load records incrementally

2. Delete studies with incorrect / changed studyid

3. Handle logical deletions

4. Create Therapeutic Area level star schema

5. Create Compound level star schema

6. Track reconciliation records

7. Track reconciliation comments

..and assist us in up-versioning Medical Dictionary Data

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Using SDTM Domains for Data Pooling
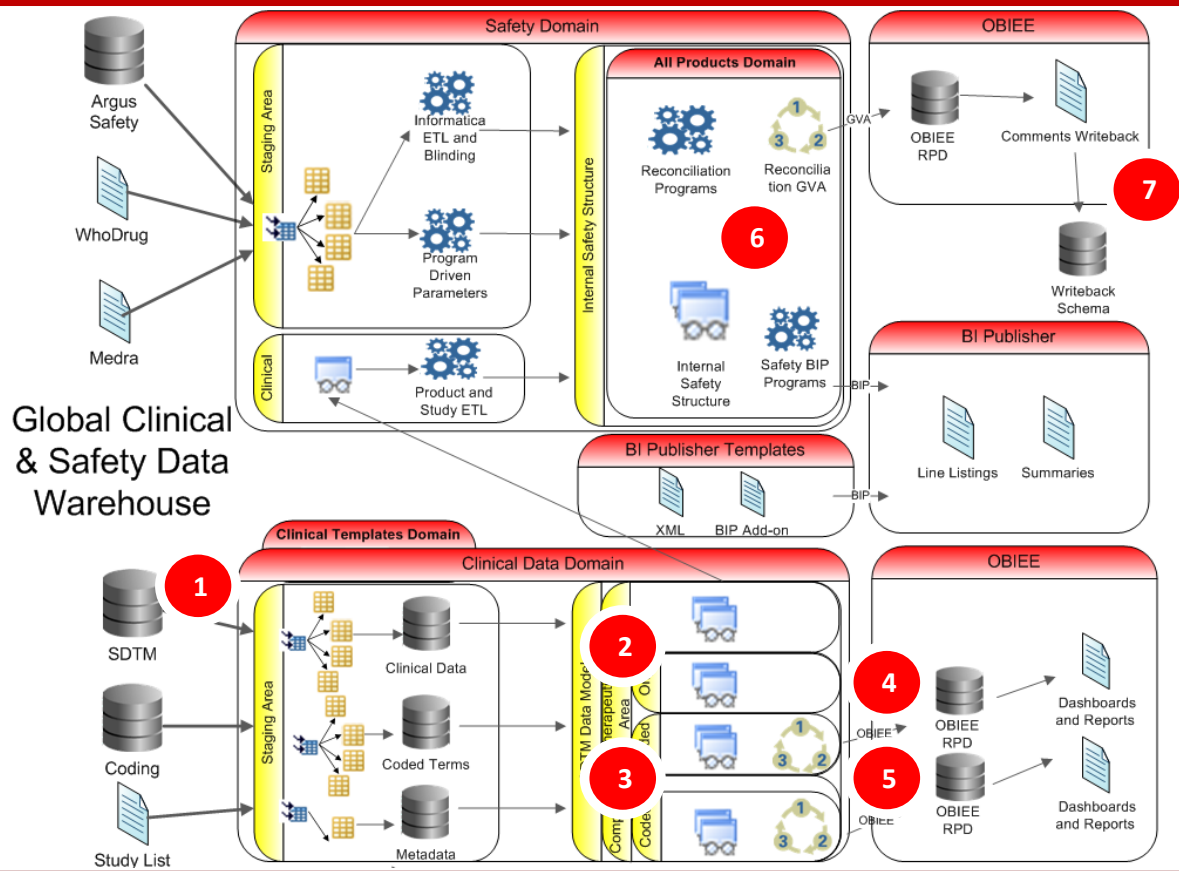
Birth of a Star Schema

Creation and population of the Fact table:

Complete the star schema joins to add the dimensions

Include keys for all of the satellite tables

Create logical tables to include SUPP domains

Limit columns to derived and key variables only

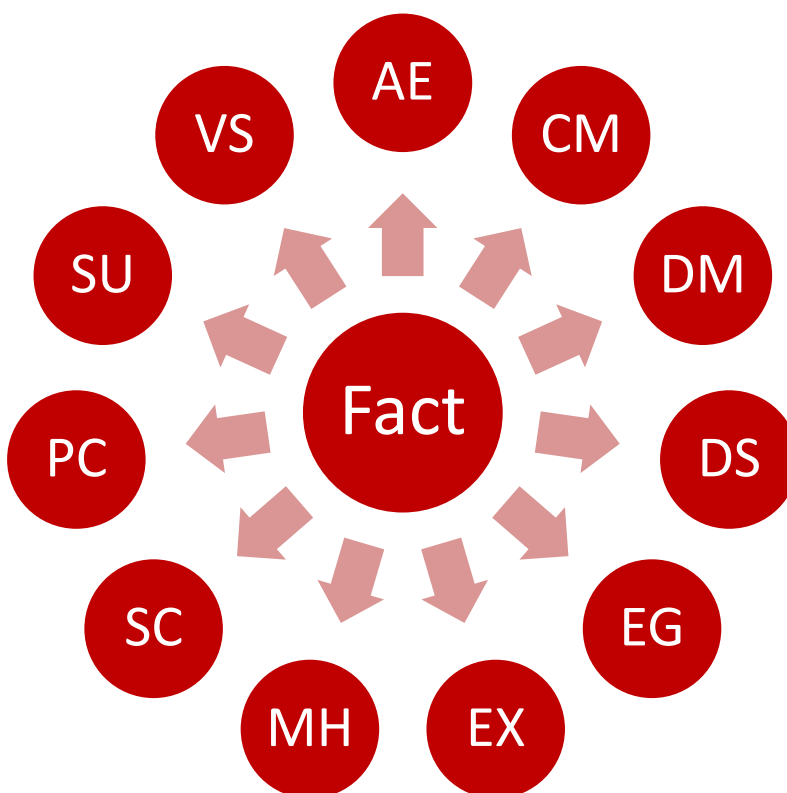Avoid destructive changes to ensure access to historical point in time data

Dimensions may evolve, but the fact table and joins do not

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Populating a Fact Table

Fact table contains SDTM keys

Outer joins on all satellite tables

User can start at any table, and collect data from any combination

Derived Variables and Analyses - Definers

Definers use the BI interface to design and develop reports:

Definers create analysis variables, analyses, reports, compile dashboards and add writeback sections

Definers can select any variable from any table without joins

Expression builder to create measures and derived variables

Measures can be defined as part of the analysis, without changing the underlying data structures

Writeback can be enabled for comment tracking

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Dashboards and Delivery - Consumers

Consumers view, report on, comment on, and export data:

Access dashboards containing multiple analyses

Externally accessible, reports and data available anywhere

Access to dashboards and data is limited by data warehouse role

Use selection prompts to retrieve correct analysis set

Easy to export data to excel, csv, ppt, pdf etc.

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Dashboards and Delivery - Consumers

Uses of the warehouse include:

- ➢ Responding to regulatory queries

- ➢ Cross-study analysis

- ➢ Data reconciliation

- ➢ Ongoing medical review

- ➢ Streamlined statistical analysis for submission

- ➢ Modeling of protocol design and trial simulation

- ➢ Safety monitoring and signal detection

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Dashboards and Delivery - Reconciliation

Find out more!

Contact us

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